WRP Asia Pacific Sdn Bhd
147817V

K002064

510(K) Summary

NOV 2 8 2000

1.0 Premarket Notification 510(k) Submission Applicant:

Name:	WRP ASIA PACIFIC SDN BHD (Reg. No.: 147817 V)
Street Address:	Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Country:	MALAYSIA
Phone No.:	+60 3 8706 1486
Fax No.:	+60 3 8706 1485
FDA Registration No.:	8041005
Device Listing No.:	B 076303

1.1 Activity of the applicant:

[√] Manufacturer [ ] Repacker [ ] Importer
[ ] Consultant [√] Contract Manufacturer [ ] Other

1.2 Contact Person:

Name:	Mr. Yue Wah, CHOW
Phone No.:	+60 3 8706 1486
Fax No.:	+60 3 8706 1485

2.0 Truthful and Accurate Statement: As shown in Section 1.

3.0 Indication for Use Statement: As shown in Section 2.

4.0 Trade Name: Comfit Chemo Plus Powder Free Blue Nitrile Examination Gloves, Non Sterile (Chemotherapy Drug Protection Labeling Claim)

5.0 Name and Location of ACTUAL Manufacturer:

Name:	WRP ASIA PACIFIC SDN BHD (Reg. No.: 147817 V)
Street Address:	Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Country:	MALAYSIA
Phone No.:	+60 3 8706 1486
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FDA Registration No.:	8041005
Device Listing No.:	B 076303

6.0 Labels, Labeling, and Advertising: Copy of dispenser box labeling is provided in Attachment A.

7.0 Classification Information:

7.1 Device Class: I

7.2 Substantial Equivalent Device Description: Patient Examination Glove

7.3 Product Code:

[ ] Vinyl – 80LYZ
[ ] Polymer – 80LZA
[ ] Specialty – 80LZC
[ ] Finger Cot – 80LZB
[ ] Other – 80FMC
[ ] Latex – 80LYY
[ ] Latex (powdered) – 80LYY
[ ] Latex (powder-free) – 80LYY
[ ] Latex (hypoallergenic) – 80LYY
[ ] Latex (powder-free/hypoallergenic) - 80LYY
[√] Nitirle (with chemotherapy drug protection label claim)– 80LZA
[ ] Latex (protein label claim) – 80LYY

8.0 Specifications:

Size	LENGTH, mm (minimum)	WIDTH, mm
XS	220	70 ± 10
S	220	80 ± 10
M	230	95 ± 10
L	230	111 ± 10
XL	230	115 ± 10

SINGLE WALL THICKNESS, mm (minimum)	
Finger	0.08
Palm	0.08

	BEFORE AGING	AFTER AGING at @ 70°C for 7 days
Tensile Strength	14 MPa, min	14 MPa, min
Ultimate Elongation	700 % min	500 % min

FDA Pinhole Requirements: Multiple, General Inspection Level G-II, AQL 4.0
ASTM Pinhole Requirements: Single, General Inspection Level G-I, AQL 2.5

8.1 Reference Performance Standards:

ASTM D3578-00 Adherence: [√] FULL [ ] PARTIAL

8.2 Chemotherapy Specialty Gloves:

A Chemotherapy Drugs Permeation Test Summary and a test report for resistance to permeation by commonly used chemotherapy drugs to demonstrate the gloves are safe and effective for handling chemotherapy drugs is provided in Attachment B.

9.0 Quality Assurance Testing (of Finished Gloves):

Does quality assurance conform to ALL ASTM D3578-00 procedures and FDA water leak test?

[√] YES [ ] NO

A summary of Quality Assurance Testing Procedure and Device Test Report of Compliance of finished gloves are provided in Attachments C and D.

10.0 Sterility: Are these examination gloves labeled as sterile? [ ] YES [√] NO

11.0 Finished Powder-Free Gloves:

Information to substantiate a "powder-free" claim is provided in Attachment E.

12.0 Colour Additives:

A material safety data sheet for the colour additive used and colour fastness test report are provided in Attachment F.

13.0 Glove Biocompatibility:

The Comfit Chemo Plus Powder Free Blue Nitrile Examination Glove has been sent for biocompatibility tests i.e. FDA Primary Skin Irritation Test and FDA Dermal Sensitization Test were performed on the finished gloves and the test results are provided in Attachments G and H respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2000

Mr. Yue Wah Chow
Head of Department, QA/RA
WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinngi,
43900 Sepang
Selangor Darul Ehsan
MALAYSIA

Re: K002064
Trade Name: Comfit Chemo Plus Powder Free Blue Nitrile Examination Gloves, Non Sterile (Tested For Use With Chemotherapy Drug) Labeling Claim
Regulatory Class: I
Product Code: LZA
Dated: September 29, 2000
Received: October 2, 2000

Dear Mr. Chow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: WRP Asia Pacific Sdn Bhd

510(k) Number (if known): K002064

Device Name: COMFIT CHEMO PLUS POWDER FREE BLUE NITRILE EXAMINATION GLOVES, NON STERILE (TESTED FOR USE WITH CHEMOTHERAPY DRUG) LABELING CLAIM

Indications For Use:

The Comfit Chemo Plus Powder Free Blue Nitrile ~~Examination Gloves~~, Non Sterile (Chemotherapy Drug Protection Labeling Claim) is a disposable device and is made of synthetic rubber ~~(nitrile) intended for~~ medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

The glove may also provide additional protection in other areas where users are handling certain hazardous chemicals such as commonly used chemotherapy drugs, as penetration and permeation by these drugs are resisted.

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter X
(Per 21 CFR 801.109)

Chin Sn Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002064